

ORIGINAL

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COMMENTS:

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BASF
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MR#352350

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013 FEB 25 11:01

February 25, 2013

Via Federal Express

United States Environmental Protection Agency - East
Attn: TSCA Section 8(e)
Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004



Subject: Notice in Accordance with TSCA Section 8(e): Results of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD422) study with CAS No. 140-95-4

Dear Section 8(e) Coordinator:

BASF Corporation is submitting results of a combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (OECD422) in Wistar Rats with Urea, N,N'-bis(hydroxymethyl)-, CAS No. 140-95-4 conducted by BASF SE, Ludwigshafen, Germany. The substance is a cross linker for easy care finishing of textiles.

The study has been performed with the dose levels of 0, 100, 300 and 1000 mg/kg body weight/day via gavage with 10 male and 10 female rats per dose group.

The following findings occurred:

1000 mg/kg bw/day:

Testes:

- Degeneration of spermatids (round and/or elongated in some seminiferous tubuli) in 5/5 males of Group 4 (1000 mg/kg bw/day, 4: minimal, 1: slight)
- Vacuolation of the seminiferous epithelium in 3/5 males (1: minimal, 2: slight)

Stomach:

- Increased incidence and/or severity of lymphogranulocytic inflammation of the submucosa glandular stomach in 5/8 males (2: minimal, 3: slight) and 3/5 females (minimal)

Urinary bladder:

- Diffuse hyperplasia of the urothelium in 5/5 males (2: minimal, 3: slight) and 4/5 females (3: minimal, 1: slight)

300 mg/kg bw/day:

Testes:

- Minimal unilateral vacuolation of the seminiferous epithelium in 2/5 males, considered not to be adverse

BASF Corporation
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BASF Corporation understands that reporting of the results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note the technical contact and address below and direct all correspondence regarding this submission accordingly. If you have any questions, please call (248) 948-2051.

Sincerely,

Technical Contact: Alisa Boucher

A handwritten signature in cursive script that reads "Alisa Boucher".

BASF Corporation
Product Regulatory Center of Expertise – North America
26701 Telegraph Road, Southfield, MI 48033

/enclosures

1463rd Letter.doc

From: (248) 948-2051
 Alisa Boucher
 BASF
 26701 Telegraph Road
 SOUTHFIELD, MI 48033

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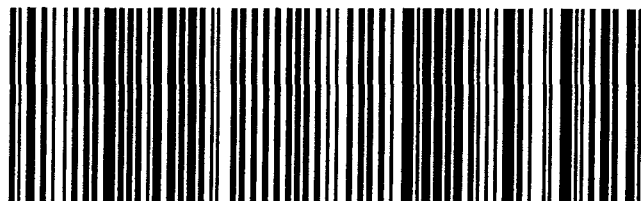
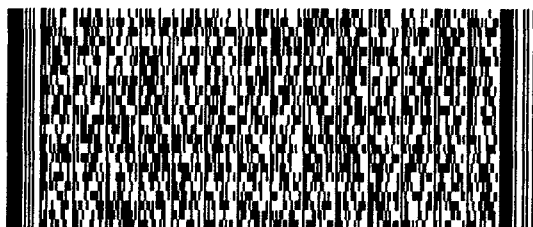
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TUE - 26 FEB 3:00P
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